PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 47434+47485	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IT2004/000575	International filing date *(day/month/year)* 21.10.2004	Priority date *(day/month/year)* 28.10.2003
International Patent Classification (IPC) or both national classification and IPC G01N35/02, G01N15/05		
Applicant DIESSE DIAGNOSTICA SENESE S.P.A.et al.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.07.2005	08.12.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Cantalapiedra, I Telephone No. +31 70 340-4260

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT2004/000575

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-31	as originally filed

Claims, Numbers

1, 10-34, 36-40	as originally filed
2-9, 35	as amended (together with any statement) under Art. 19 PCT

Drawings, Sheets

1/16-16/16	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 41-76

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-40
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-40
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-40
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1) Reference is made to the following documents:

D1: EP-A-0 391 861 (DIESSE DIAGNOSTICA SENESE S.R.L) 10 October 1990 (1990-10-10)
D2: US-A-5 526 705 (SKOTNIKOV ET AL) 18 June 1996 (1996-06-18)

2) The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

A device for measuring the sedimentation rate in biological fluids (D1, abstract), and specially the rate of erythrocyte sedimentation in blood samples, comprising: holders for test tubes containing samples of biological fluid (D1, fig 1); agitator devices for agitating said test tubes; at least one detector for detecting the levels inside said test tubes (D1, col 4, line 45 to col 5, line 41).

The subject-matter of claim 1 therefore differs from this known D1 in that: the holders are formed in a continuos flexible member defining a closed path along which said agitator devices and said at least one detector are arranged.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem solved by this special technical feature can therefore be construed as: to have an option of conveying the maximum number of holders possible while reducing the space necessary and be able to agitate the test tubes along the closed path.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

D1 suggests to have a rigid supporting member holding all the test tubes and to agitate all the test tubes together. The subject-matter of claim 1 is considered inventive because it defines a device that allows for a more efficient spacial distribution of the test tubes and an

agitation of the tubes concerned in the analysis.

D2 also discloses a flexible closed path including tube holders, but this document does not concerns the field of ESR measurements and it uses agitators devices in order to stirr the content of the test tubes but not the tubes themselfs. Therefore it is considered that a combination of the features of both documents is not obvious.

2.1) The independent method claim 35 is also considered novel and inventive, the features therein being equivalent to the already discussed claim 1, mutatis-mutandis.

3) Claims 2-34 and 36-40 are dependent on claim 1 or 35 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Amendments under Art. 34 PCT

Amended CLAIMS

1. Device for measuring the sedimentation rate in biological fluids, and especially the rate of erythrocyte sedimentation in blood samples, comprising: holders for test tubes containing samples of biological fluids; agitator devices for agitating said test tubes; at least one detector for detecting the levels inside said test tubes; characterized in that said holders are formed in a continuous flexible member defining a closed path, along which said agitator devices and said at least one detector are arranged.

2. Device as in one or more of the previous claims, characterized in that said agitator devices are arranged and made to induce the oscillation of said holders.

3. Device as in claim 1 or 2, characterized in that the following are arranged along said closed path: at least one agitating area, wherein said agitator devices are provided; at least one sedimentation area; and at least one reading area wherein said detector is installed.

4. Device as in claim 1 or 2 or 3, characterized in that said flexible member defines a path lying on a substantially horizontal plane.

5. Device as in any one of the previous claims, characterized in that said holders are composed of elements interconnected to form a flexible chain member.

6. Device as in claim 5, characterized in that each of said elements comprises a single seat for a respective test tube.

7. Device as in claim 5 or 6, characterized in that the elements forming said flexible member are connected together by means of couplings that enable consecutive elements to rotate with respect to each other so as to make single elements depart from the plane on which the flexible member lies.

8. Device as in claim 7, characterized in that said couplings are composed of spherical joints.

9. Device as in claims 2 and 4, characterized in that said agitator devices are made and arranged to induce the oscillation of said elements forming the flexible chain member, outside the plane on which the flexible

member lies.

10. Device as in claim 9, characterized in that said agitator devices include guides in which the elements forming said continuous flexible chain member are engaged, thereby causing the oscillation of said elements.

11. Device as in claim 10, characterized in that said elements have sliding shoes engaging in said guides.

12. Device as in claim 9, 10 or 11, characterized in that said agitator devices include fixed guides, extending along a portion of the path covered by said flexible member, that are made and arranged so that the elements moving along them are forced to oscillate outside the plane on which said continuous flexible member lies.

13. Device as in claim 9, 10 or 11, characterized in that said agitator devices include mobile guides, extending along a portion of the path covered by said flexible member, wherein said elements forming the flexible member are engaged, said guides being made and arranged to induce, with their motion, an oscillation of the elements attached thereto outside the plane on which the continuous flexible member lies.

14. Device as in one or more of the claims 9, 10, 11 and 13, characterized in that said agitator devices comprise a rotor coaxial to a stretch of the path of said flexible member and provided with elements for engaging the holders that come to be along said stretch along the path of the flexible member, said rotor being capable of a rotating or oscillating movement around its own axis.

15. Device as in claim 14, characterized in that said engaging elements are in the form of guides within which said holders forming the continuous flexible member are slidingly engaged.

16. Device as in one or more of the previous claims, characterized in that a first detector is arranged along said closed path, downstream from the agitator devices, and at least one second detector is arranged further along said path, downstream from a portion of path defining a first sedimentation area.

17. Device as in claim 16, characterized by a third detector arranged along said path, downstream from a further portion of path defining a second

sedimentation area.

18. Device as in one or more of the previous claims, characterized in that said continuous flexible member comprises a transponder associated with each test-tube holder.

19. Device as in claims 4 and 18, characterized in that each of said elements is associated with a respective transponder.

20. Device as in claim 18 or 19, characterized in that along said path there are one or more stations for scanning said transponders.

21. Device as in one or more of the previous claims, characterized in that along said closed path there is at least one extractor, for removing the test tubes from said holders.

22. Device as in claim 21, characterized in that along said closed path there are two extractors for removing the test tubes from said holders and distributing them in respective containers.

23. Device as in one or more of the previous claims, characterized in that automatic manipulators are provided for automatically inserting the test tubes in said holders.

24. Device as in claim 23, characterized in that said manipulators are arranged and made to collect single test tubes from a rack of test tubes and to insert said test tubes in said holders.

25. Device as in one or more of the previous claims, characterized in that it includes a setup unit for preparing the test tubes for insertion in said holders.

26. Device as in claim 25, characterized in that said setup unit is situated above said continuous flexible member.

27. Device as in claim 25 or 26, characterized in that said setup unit comprises a reading station for automatically reading labels attached to said test tubes, to ascertain in each case whether they must undergo a measurement of the sedimentation rate of the sample contained therein.

28. Device as in claims 24 and 27, characterized in that said manipulators are controlled and operated by a central unit as a function of information provided for each test tube by said reading stations, to transfer the test tubes in which the sedimentation rate must be measured from the

rack to a corresponding holder.

29. Device as in one or more of the claims 25 to 28, characterized in that said setup unit comprises at least one first conveyor for moving a plurality of racks containing test tubes with samples of biological fluid to analyze.

30. Device as in claims 27 and 29, characterized in that said setup unit comprises a first transfer unit for removing single racks from said first conveyor and transferring them to said reading station.

31. Device as in one or more of the claims 24 to 30, characterized in that said manipulators include a lower push bar coming to bear on the test tubes contained in the racks in order to slide said test tubes partially out of said racks, and a mobile clamp for removing the test tubes from the respective racks and inserting them in corresponding holders in the continuous flexible member.

32. Device as in claim 29 at least, characterized in that the setup unit includes a second conveyor for moving a plurality of racks and a second transfer device for transferring the racks from the second to the first of said conveyors.

33. Device as in claim 32, characterized in that the first transfer device transfers the racks from the first conveyor to the reading station and from there to the second conveyor.

34. Device as in one or more of the claims 29 to 33, characterized in that means for identifying the status of each rack are associated with at least one of said first and/or second conveyors of the setup unit.

35. Method for measuring the sedimentation rate in biological fluids, and the rate of erythrocyte sedimentation in blood samples in particular, comprising: an agitation phase, in which test tubes containing biological fluids are agitated; a sample sedimentation phase; and a phase for reading the level of the sediment inside said test tubes; characterized in that: said test tubes are placed in respective holders forming a continuous flexible member; said continuous flexible member is advanced along a closed path; and the single test tubes go through said agitation, sedimentation and reading phases in areas sequentially arranged along said closed path.

36. Method as in claim 35, characterized in that said test tubes are

agitated by rotating said holders in relation to each other around a substantially horizontal axis.

37. Method as in claim 35 or 36, characterized in that, along said path, two readings are taken on the biological samples in each test tube, the first when it leaves the agitation area and the second at the end of the sedimentation area.

38. Method as in claim 37, characterized in that, after the reading of the level of sediment, said samples undergo a second sedimentation phase and a further reading of the level of sediment after said second sedimentation phase.

39. Method as in one or more of the claims 35 to 38, characterized in that said test tubes are test tubes for complete blood counts.

40. Method as in claim 39, characterized in that: said test tubes are sequentially fed to a station for reading the labels attached to said test tubes; for each test tube, it is ascertained whether the sample contained therein is to undergo a sedimentation rate measurement; the test tubes in which the sedimentation rate is to be measured are transferred to said holders.